

COVID-19 Monoclonal Antibodies

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IOWA DEPARTMENT OF PUBLIC HEALTH

Monoclonal Antibodies (mAbs)

- Bamlanivimab (Eli Lilly) and casirivimab/imdevimab (Regeneron) are available under EUA
- mAbs directly neutralize the COVID-19 virus and are intended to prevent progression of disease
- Likely most effective when given early in infection
- Product delivered via single administration (i.e., IV infusion)
 - 60-minute administration duration
 - 60-minute observation period



Monoclonal Antibody Patients

- Not authorized for use in patients:
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

- EUAs for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
 - with positive results of direct SARS-CoV-2 viral testing, and
 - who are **at high risk** of progressing to severe COVID-19 and/or hospitalization.



Monoclonal Antibody Patients

High risk defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have cardiovascular disease; OR hypertension; OR chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 17 years of age AND have BMI ≥85th percentile for their age and gender based on CDC growth charts; OR sickle cell disease; OR congenital or acquired heart disease; OR neurodevelopmental disorders, for example, cerebral palsy; OR a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19); OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control



Vaccine and Monoclonal Antibodies

Can I get a COVID-19 vaccine if I have had antibody treatment?

We do not yet know how effective vaccines are in someone who has previously received an antibody treatment for a COVID-19 infection, or whether the antibody treatment could interfere with your body's own immune response to a vaccine. Once you have had COVID-19, you are very unlikely to be reinfected for three months afterward. So, if you receive an antibody treatment, you should delay receiving a vaccine for three months as a precaution. See CDC: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

Can I have antibody treatment if I have been vaccinated?

In the absence of data we are only able to provide suggestions for consideration by providers; the ultimate decision on how to treat an individual in this situation ultimately rests with the provider.

For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells.

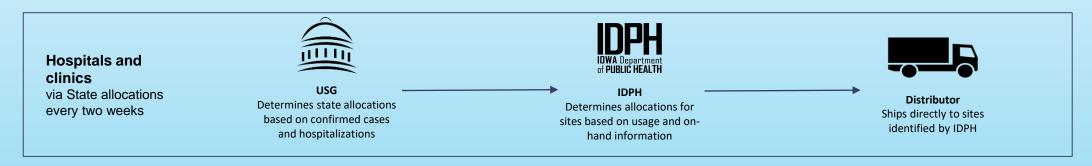
We [FDA] recommend that subsequent vaccination, if administered, occur at least two weeks following the administration of a monoclonal antibody.

These recommendations are subject to change as additional data become available.



Allocation of Monoclonal Antibodies

Until the national supply of mAbs is sufficient, the Iowa Department of Public Health and the United States government will help facilitate allocation across Iowa.



Long-term care pharmacies

via Special Projects for Equitable and Efficient Distribution (SPEED)



IDPH

Receives request and sends request for pharmacy to receive **bamlanivimab**.



USG

Receives requests from IDPH, contacts pharmacy to coordinate receipt of bamlanivimab, and places orders to distributor.



DistributorShips directly to pharmacy.



1. Review EUA and Provider Fact Sheet



November 10, 2020

Eli Lilly and Company Attention: Christine Phillips, PhD, RAC Advisor Global Regulatory Affairs - US Lilly Corporate Center Drop Code 2543 Indianapolis, IN 46285

Dear Ms. Phillips:

This letter is in response to Eli Lilly and Company's ("Lilly") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that thas a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.1 On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstance exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.²

Bamlanivimab is a neutralizing IgGI monoclonal antibody that binds to the receptor binding domain of the spike protein of SARS-CoV-2. It is an investigational drug and is not currently approved for any indication.

Based on review of the topline data from the planned interim analysis of Trial J2W-MC-PYAB, also called BLAZE-1 (NcT04427501), an ongoing randomized, double-blind, placebo-controlled, Phase 2 dose finding trial of bamlanivimab monotherapy in outpatients with mild to moderate COVID-19, it is reasonable to believe that bamlanivimab may be effective for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when

FACT SHEET FOR HEALTH CARE PROVIDERS
EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB

AUTHORIZED USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamianivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- · Bamlanivimab is not authorized for use in patients
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Bamlanivimab has been authorized by FDA for the emergency uses described above. Bamlanivimab is not FDA-approved for these uses.

Bamlanivimab is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

This EUA is for the use of the unapproved product bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization [see Limitations of Authorized Use].

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- · Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- · Are currently receiving immunosuppressive treatment
- Are ≥65 years of age

https://www.fda.gov/media/143602/download

https://www.fda.gov/media/143603/download



¹ U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C, 23 600bb-3. February 4, 2020.

² U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Programmin Section 364(b) of the Federal Food, Drug, and Cosmetic Act, 21U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

2. Check whether your pharmacy has bamlanivimab

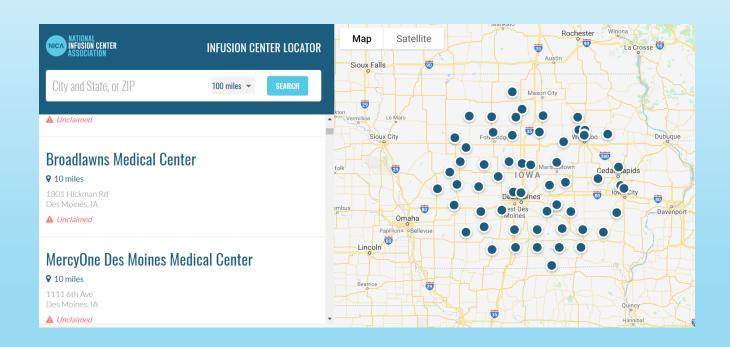
Pharmacy	City
Guardian Pharmacy of Iowa LLC	Ankeny
NuCara LTC Pharmacy #3	Iowa City
NuCara LTC Pharmacy #4	Waterloo
NuCara LTC Pharmacy #5	Ottumwa
Omnicare of the Quad Cities	Davenport
Omnicare of Urbandale	Urbandale
PCA Iowa Rx, LLC dba PCA Des Moines	
Pharmacy	Urbandale
PHARMERICA	Urbandale
PHARMSCRIPT OF IA LLC	Urbandale

- Some long term care pharmacies currently have bamlanivimab.
- Check with your pharmacy to see if bamlanivimab is available.

Long term care pharmacies that have been shipped bamlanivimab as of 1/24/21.



3. Explore other options for treating patients



- If your pharmacy does not have bamlanivimab, check whether your local hospital administers mAbs using the locator tool. If your local hospital administers
- mAbs:
 - Could patients be treated at the hospital?
 - Could the hospital treat patients
- at your facility?

 If hospital involvement is not the best option for your facility, assess your facility's readiness to prepare and administer bamlanivimab.



4. Readiness checklist

Readiness checklist: Administration of outpatient mAbs under EUA



Allocate dedicated space and develop plan to manage patient flow

- Clear process for patients that are coming to clinical site including scheduling requirements
- □ Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines'
- Dedicated room available for treatment



Ensure dedicated source of supplies; which may be difficult to procure

- Needed infusion components obtained
 - ☐ Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications



Assign sufficient personnel to meet expected demand

- ☐ Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist
 - Likely need dedicated team to treat patients



Prepare for drug administration process

- ☐ Pre-visit: Clear treatment and monitoring plan developed for during infusion
- ☐ Treatment: 1-hour treatment and 1-hour post-treatment observation
 - Emergency protocol defined for addressing potential infusion reactions or complications
- ☐ Post-treatment: Clear process for patient follow-up defined using telemedicine as possible



Ensure process for reimbursement in place (non-drug administrative costs)



Prepare for reporting needs for adverse events and record keeping

Also consider:

- Role of pharmacy
- Role of compounding pharmacy



5. Request bamlanivimab

When your facility is ready, submit a <u>request to receive bamlanivimab</u>. If your facility has an urgent need, please contact <u>cassie.kennedy@idph.iowa.gov</u> or (515) 330-5755.

Special Projects for Equitable and Efficient Distribution (SPEED)







IDPH

Receives request and sends request for pharmacy to receive bamlanivimab.

USG

Receives requests from IDPH, contacts pharmacy to coordinate receipt of bamlanivimab, and places orders to distributor.

Distributor

Ships directly to pharmacy.



Helpful Links

General Resources

Operation Warp Speed Monoclonal Antibody Playbook

National Infusion Center Association COVID-19 Antibody

Treatment Resource Center

IDPH Monoclonal Antibodies

HHS ASPR Outpatient Therapeutics Mini-Series

Bamlanivimab (Eli Lilly)

Bamlanivimab Letter of Authorization (EUA)

Bamlanivimab Provider Fact Sheet

FDA Frequently Asked Questions on the EUA for Bamlanivimab

Lilly Bamlanivimab Information

Lilly Bamlanivimab Antibody Playbook

Bamlanivimab Pocket Resource Card

Bamlanivimab Overview, Allocation, and Distribution

Casirivimab/Imdevimab (Regeneron)

Casirivimab/imdevimab Letter of Authorization (EUA)

Casirivimab/imdevimab Provider Fact Sheet

FDA Frequently Asked Questions on the EUA for Casirivimab +

Imdevimab

Important Prescribing Information: A Letter from Regeneron to

Healthcare Providers on Preventing Medication Errors

Regeneron Casirivimab/imdevimab Information

Regeneron Casirivimab/imdevimab Guidebook

Casirivimab/imdevimab Overview, Allocation and Distribution

Billing and Coding

COVID-19 Frequently Asked Questions on Medicare Fee-for-

Service Billing

CMS Monoclonal Antibody COVID-19 Infusion

Insurance Coverage of Monoclonal Antibody Treatment

Drug Supply Chain Security Act (DSCSA)



Contact

For questions, please contact Cassie Kennedy at cassie.kennedy@idph.iowa.gov or (515) 330-5755.

